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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,359	07/23/2003	Daniel M. Deaton	900001-2115	8226

7590 12/13/2005
Kos Life Sciences, Inc.
1001 Brickell Bay Drive
Miami, FL 33131



EXAMINER

BUNIN, ANDREW M

ART UNIT PAPER NUMBER

3743

DATE MAILED: 12/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/625,359	Applicant(s) DEATON ET AL.	
	Examiner Andrew M. Bunin	Art Unit 3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-54 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-54 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6, 8, and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by O'Connor (US 6029659). O'Connor discloses an apparatus for dispensing medication comprising at least one canister 11 containing the medication to be dispensed, the canister 11 being movable in a first and a second direction. O'Connor continues to disclose a mouthpiece 12 providing a point of dispensation for the medication from the canister 11 to a user when the canister is moved in a first direction. In addition, O'Connor discloses a switch means 50 for completing an electrical circuit when the canister 11 moves in a first direction and opening the electrical circuit when the canister 11 moves in a second direction, wherein the switch means 50 is oriented to enable operational connectivity with the canister or canister discharge (see Figure 7). O'Connor includes a counter module 40 for performing a count upon the closure of the electrical circuit and displaying a dispensation history (41) of the medication in the canister 11. O'Connor discloses a seal 718 isolating the counter module 40 from the mouthpiece and the canister to prevent contamination as shown in Figure 7.

As for claims 2-4 and 6, O'Connor discloses the dispensation history that includes the number of doses of medication remaining in the canister (column 3, lines 58-61). In

Art Unit: 3743

addition, O'Connor teaches the history including the number of doses taken of a dosage sequence the number of doses taken over a period of time (column 5, lines 19-24 and column 4, lines 52-55). O'Connor continues to disclose the dispensation history including time since the last dispensation of the medication (column 5, lines 46-55).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Connor. It would have been obvious to a person having ordinary skill in the art at the time of the invention to allow this device to be capable of varying the period of time for a dosage in order for the device to be reused with different medicines of varying dosage requirements.

Claims 7, 9, 40, and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Connor. O'Connor has disclosed the display portion 41 of the counter module 40 is on the back of the mouthpiece as shown in Figure 6. However, placing the display portion on the front of the mouthpiece or on the side of the mouthpiece are both equivalents of placing the display portion on the back of the mouthpiece. Accordingly, the examiner considers the selection of such to be mere

obvious matter of design choice and as such does not patently distinguish these claims over the prior art.

Claims 10, 11, and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Connor in view of Rand et al. (US 6431168). O'Connor has taught everything except the switch means including an electrically conductive contact imbedded in the seal. However, Rand et al. teach a similar apparatus for dispensing medication that includes a switch means 44 with an electrically conductive contact 46/47 imbedded in the seal 40. Therefore, it would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the device of O'Connor to replace this switch means with the switch means taught by Rand et al. in order to increase the reaction speed of the switch from movement of the canister as well as improve the accuracy of having a switch react via conductive contact versus force of contact.

As for claims 11 and 12, O'Connor discloses a portion of the counter module 40 disposed external to the mouthpiece 12 as shown in Figure 5. It is considered a mechanical equivalent to place a portion of the counter module within the mouthpiece. In addition, Rand et al. device teaches the counter module as being partially disposed within the mouthpiece especially if the mouthpiece includes portion 3 until 20. Accordingly, the examiner considers the selection of such to be mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art.

Claims 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Connor in view of Rand et al. O'Connor discloses everything except the seal including

Art Unit: 3743

a ramp that acts upon the switch. However, Rand et al. teaches the seal 40 passing above switch 44 including a ramp 47/46 that act upon the switch means 44 when the canister 2 is moved in the first direction as shown in Figures 8 and 9. In addition, Rand et al. teaches the switch means 44 as being mounted on a circuit board 49 (column 8, lines 17-22) and is acted upon by a ferrule portion 11 of the canister 2, the switch means 44 being isolated from the canister by a second seal 5 (column 4, lines 12-20). Rand et al. also teaches the seal 40 being made of conductive material (sections 47/46). Therefore, it would have been obvious to a person having ordinary skill in the art at the time of the invention to modify O'Connor with the switch means system of Rand et al. in order to improve the reaction time of the circuit.

Claims 16-19 and 22-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Connor in view of Jewett et al. (US 5544647). O'Connor discloses everything except the switch means as being a water resistant dome switch. However, Jewett et al. teach a similar device to O'Connor including a switch means 42 that is a water resistant dome switch (column 7, lines 45-55). Jewett et al. continues to disclose the dome switch 42 as being mounted substantially parallel to an axis of travel of the canister 16 and is capable of being acted upon by a ferrule of the canister (Figure 3). Jewett et al. also teaches the dome switch 42 as being mounted on a platform (two lines connected to 46 in Figure 4) that extends perpendicular to the axis of travel of the canister 16 into the mouthpiece 22 and is acted upon by an end portion of the canister as shown in Figures 1 and 3. As for claim 19, although Jewett et al. don't explicitly teach the dome switch as being mounted on a top surface of an actuator sump, this

would be equivalent to placing the dome switch on a platform as stated above.

Therefore, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patentably distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

Claims 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Connor in view of Jewett et al. and further in view of Rand et al. O'Connor and Jewett et al. teach everything except the switch means as being comprised of two open contacts that are in electrical communication with the counter module. However, Rand et al. disclose the switch means comprising two open contacts (46 and 47) that are in electrical communication with the counter module and a conductive surface of the canister 2 to close the contacts 46/47 when the canister moves in the first direction (column 8, lines 8-33). Rand et al. continues to teach the two open contacts 46/47 are located on a top surface of an actuator sump and are acted upon by a metallic end portion of the canister 2 as shown in Figures 8 and 9. Therefore, it would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the device taught in the prior art to use a direct electrical connection between the counter module and a canister in order to increase the accuracy and speed of reaction for each dosage.

As for claims 22 and 23, Jewett et al. continue to disclose the dome switch 42 as being acted upon by the actuator as the canister 16 moves in the first direction shown in Figure 3. Placing the dome switch on an actuator sump or on an exterior surface of the mouthpiece are both considered mechanical equivalents to placing the dome switch on

Art Unit: 3743

a platform. Therefore, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

As for claims 24-31, Jewett et al. discloses the switch means as being formed of a movement sensor (column 9, lines 1-7). In addition, Jewett et al. teaches the movement sensor as being a light sensor, the light sensor emitting light and receiving a reflected signal, upon movement of the canister the reflected signal is altered and the altered signal is detected by the sensor providing input to the circuitry and changes the count (column 7, lines 63-67). The sensor is located to act upon and detect a changing position of the canister as it is moved in the first direction (column 8, lines 12-16). Jewett et al. also teaches the movement sensor as being an acoustic sensor, the acoustic sensor emitting an acoustic signal and receiving a reflected signal, upon movement of the canister the reflected signal is altered, and the altered signal is detected by the sensor closing contacts housed therein (column 6, lines 42-51). The acoustic sensor taught by Jewett et al. is capable of sensing the acoustic signature of the aerosolization of a metered dose dispensation (column 6, lines 42-44). Lastly, Jewett et al. teaches the movement sensor as being a magnet sensor, upon movement of the canister the magnetic signature of the canister is altered which is detected by the sensor providing input to the circuitry and changes the count (column 8, lines 53-67). As stated above, the sensor is "triggered" upon detection of a changing geometry of the canister as it is moved in the first direction (column 8, lines 12-16). Therefore, it would have been obvious to a person having ordinary skill in the art at the time of the invention

Art Unit: 3743

to modify O'connor to include the sensor and dome switch taught by Jewett et al. in order to quickly and efficiently keep track of the dosage for a user.

Claims 24, 32 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'connor in view of Mishelevich et al. (US 5363842). O'connor discloses everything except the switch means as being formed of a movement sensor.

Mishelevich et al. teach a switch means with a motion sensor 222 that is a pressure sensor 240/230 and located in an actuator sump for detecting a change in pressure upon the dispensation of the medication from the canister. The pressure sensor taught by Mishelevich et al. is considered a mechanical equivalent of the other movement sensors taught by Jewett et al. for improving the technology of a counter device.

Therefore, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over O'connor in view of Rand et al. O'connor has taught everything except a ramp seal isolating the switch means from the canister. However, Rand et al. teaches a ramp seal 46/47 connected to body 40 isolating the switch means 44 from the canister 2 to prevent contamination, wherein the ramp seal 46/47 is acted upon by the canister upon movement of the canister in the first direction and wherein the ramp seal 46/47 acts on the switch means to close the electrical circuit as shown in Figures 8 and 9. Therefore, it would have been obvious to a person having ordinary skill in the art at the time of the

invention to modify O'connor with the switch means system of Rand et al. in order to improve the reaction time of the circuit.

Claims 35-37, 39, and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'connor.

As for claims 35-37 and 39, O'connor discloses the dispensation history that includes the number of doses of medication remaining in the canister (column 3, lines 58-61). In addition, O'connor teaches the history including the number of doses taken of a dosage sequence the number of doses taken over a period of time (column 5, lines 19-24 and column 4, lines 52-55). O'connor continues to disclose the dispensation history including time since the last dispensation of the medication (column 5, lines 46-55).

Claims 44-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'connor. O'connor discloses a ferrule portion of the canister 11 acting upon a ramp seal 51. O'connor continues to teach the counter 40 and ramp seal 51 as being formed in a common component. In addition, O'connor discloses a sump for a nozzle of the canister wherein the counter, ramp seal and sump are formed as a common component as shown in Figure 5. The device's common component of O'connor is capable of being injection moldable. In addition, this device's common component is capable of being adaptable to canister holders for a variety of canister shapes and sizes. O'connor's common component is adaptable to canister holders for a variety of canister shapes and sizes. In addition, it is considered well known in the art that this device is adaptable to canister holders for a variety of canister shapes and sizes for

Art Unit: 3743

many different users. This device also includes the components including a canister holder, a canister, a mouthpiece, and a counter, wherein the counter is adaptable for use with a canister holder, canister, and a mouthpiece capable of being made of a variety of sizes and shapes. Therefore, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: US 6446627, US 6138669, and US 5505192

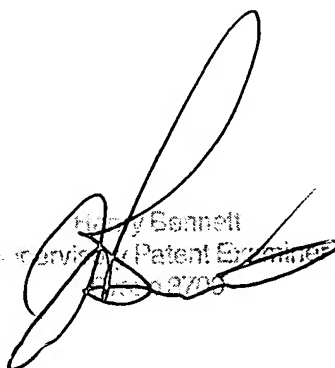
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew M. Bunin whose telephone number is (571)272-4801. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on (571)272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3743

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


AMB
12/07/05


Gregory Bennett
Supervising Patent Examiner
12/07/05

Notice of References Cited	Application/Control No. 10/625,359	Applicant(s)/Patent Under Reexamination DEATON ET AL.	
	Examiner Andrew M. Bunin	Art Unit 3743	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-6,029,659	02-2000	O'Connor, James A.	128/203.12
*	B	US-6,431,168	08-2002	Rand et al.	128/200.23
*	C	US-5,544,647	08-1996	Jewett et al.	128/200.23
*	D	US-6,431,168	08-2002	Rand et al.	128/200.23
*	E	US-5,363,842	11-1994	Mishelevich et al.	128/200.14
*	F	US-5,622,163	04-1997	Jewett et al.	128/200.23
*	G	US-6,446,627	09-2002	Bowman et al.	128/200.23
*	H	US-6,138,669	10-2000	Rocci et al.	128/200.23
*	I	US-5,505,192	04-1996	Samiotes et al.	128/200.14
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

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NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
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	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
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